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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,748	06/21/2006	Fabio Stradella	Q92693	1777
23373 SUGHRUE MI	7590 02/02/200 ON, PLLC	EXAMINER		
2100 PENNSYLVANIA AVENUE, N.W.			HAGEDORN, MICHAEL E	
	SUITE 800 WASHINGTON, DC 20037			PAPER NUMBER
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# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
	10/564,748	STRADELLA ET AL.			
Office Action Summary	Examiner	Art Unit			
	Michael Hagedorn	3754			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status					
Responsive to communication(s) filed on <u>21 Ju</u> This action is <b>FINAL</b> . 2b)☑ This     Since this application is in condition for allowar closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro				
Disposition of Claims					
4)  Claim(s) 1 - 40 is/are pending in the application 4a) Of the above claim(s) is/are withdrav 5)  Claim(s) is/are allowed. 6)  Claim(s) 1 - 40 is/are rejected. 7)  Claim(s) is/are objected to. 8)  Claim(s) are subject to restriction and/or Application Papers 9)  The specification is objected to by the Examine 10)  The drawing(s) filed on 17 January 2006 is/are Applicant may not request that any objection to the or	vn from consideration. relection requirement. r. r. a) accepted or b) objected	•			
Replacement drawing sheet(s) including the correcti  11) The oath or declaration is objected to by the Ex-		• •			
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No. 10/564,748.  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.					
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 17 January 2006.	4)  Interview Summary Paper No(s)/Mail Da 5)  Notice of Informal P 6)  Other:	nte			

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### **DETAILED ACTION**

## **Drawings**

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "spring" attached to a transmission element must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

## **Double Patenting**

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1 – 40 are rejected on the ground of nonstatutory double patenting over claims 1 - 15 of U. S. Patent No. 7,275,660 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

4. Claims 1 – 40 are provisionally rejected on the ground of nonstatutory double patenting over claims 1 - 19 of copending Application No. 10/564,315. This is a

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provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

5. Claims 1 – 40 are provisionally rejected on the ground of nonstatutory double patenting over claims 1 - 19 of copending Application No. 10/542,507. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

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## Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 7. Claims 38 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The "transmission element attached to a spring" is not disclosed in the specification nor is it shown in the drawings.
- 8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

  The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 9. Claims 1-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 10. The term "one part" in claim 1, 8, 20, 21, 30, 37 is a relative term which renders the claim indefinite. The term "one part" is not defined in the claims, the specification and does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

### Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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- 12. Claim 1, 8, 15, 19, 20, 21, 30, 36 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Ouyang et al. (US Patent Publication 2004/0149773).
- 13. In re claim 1 and 21, Ouyang et al. discloses a dose indicator (A) for fluid product dispensing device (1) comprising at least one rotary counting means (142) which can be moved in rotation, said at least one counting means comprising indication means (141) indicating the number of doses dispensed or remaining to be dispensed, said at least one counting means being actuated by an actuating member (143) itself actuated by a transmission element (144) adapted to cooperate with one part (149) of said dispensing device on each actuation thereof, characterized in that said dose indicator comprises amplification means adapted to amplify the movement of said transmission element (144) on each actuation, so that the movement of said actuating member (143) is greater than the movement of said transmission element (144).
- 14. In re claim 8 and 30, Ouyang et al. discloses said transmission element (144) is a shoulder joined to a flexible lug (154) and cooperating with one part (149) of the fluid product dispensing device (1) which is mobile during actuation.
- 15. In re claim 15, Ouyang et al. discloses wherein said indication means (147) are number and/or symbols.
- 16. In re claim 19 and 36, Ouyang et al. discloses Fluid product dispensing device () comprising a product reservoir (21) and a dispensing member (22) such as a pump or

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valve mounted on said reservoir (21), characterized in that it comprises a dose indicator (A)

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17. In re claim 20 and 37, Ouyang et al. discloses wherein the dose indicator (A) is actuated by one part (149) of the dispensing device (1) which is moved during actuation of device (1) and which cooperates with a transmission element (144) of said indicator (142).

## Claim Rejections - 35 USC § 103

- 18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 20. Claims 1 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horlin (WO 01/37909 A1) in view of Fairbairn (GB 1,336,014).

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21. Horlin discloses an inhaler cartridge (4) that dispenses by pressing downwardly inside a holder channel (3) in order to trigger the dispensation (see figure 7) through passage (6), with a counter mechanism (2) with a cap (7) with a viewing window (10) to view a spiral set of number (21) to assist the user in knowing how many doses are used or left, the pin (32) is actuated when the inhaler cartridge (4) is pressed downwardly into the holder channel (3), the pin (32) flexes a tab (33) that flexes before the actuation of the inhaler cartridge (4), which in turn changes the viewed number (see figure 3a) with the use of the second relatively stiff flexible tabs (25 - 26) that actuate after the rotary wheel has commenced rotating, the control wheel prevented from over actuating by a key slot (34 - 35), which will only allow the control wheel to actuate a certain distance, the control wheel prevented from—rotating in the wrong direction by the end tabs (30 – 31), the entire counting device (2) integrated and assembled as one piece (7 – 9) (see figure 5).

However, Horlin fails to disclose the counting wheel displaceable in rotation, a slide member that is displaceable in translation, to allow the counting wheel to display rows and columns of numbers by translating the slide member at least every so often, the slide member having a projection that cooperates with a channel in the counting wheel to track, drive and translate the slide member appropriately, the channel being preferably spiral shaped, slide member and counting one integrated piece.

Although, Fairbairn with reference to figures 1 - 3 teaches a slide member (8) that is integrated with a counting wheel (4), the slide member having a viewing window (12) that shows the various rows and columns of numbers on the counting wheel at the

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appropriate intervals of actuation, the slide member's viewing window moving by the engagements and movement of the spiral channel (7) on the counting wheel that interacts with the tooth (9) from the slide member (8). Therefore, it would have been obvious to one ordinary skill in the art at the time of the invention to implement Fairbairn's teaching into Horlin's because Fairbairn teaches a way to utilize the entire counting wheel and not just its outer rim for counting dosages, which can ultimately lead to a smaller counter, which is advantageous in a variety of applications.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hagedorn whose telephone number is (571)270-5705. The examiner can normally be reached on 7am - 5pm; Mon thru Fri except federal holidays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (571)270-4720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. H./ Examiner, Art Unit 3754

/Kevin P. Shaver/ Supervisory Patent Examiner, Art Unit 3754